FDA U.S. FOOD & DRUG ADMINISTRATION

October 18, 2019

Angelia Inscoe
Founder and CEO
Induction Therapies, LLC
3600 Chamberlain Lane, Ste 336
Louisville, Kentucky 40241
Document Number: CPT1901026

Dear Ms. Inscoe:

It has come to our attention that you may be marketing the Collagen P.I.N, which appears to meet the definition of a device as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act (FD&C Act), in a manner that potentially violates the FD&C Act.

Specifically, we have conducted a review of our files, and have been unable to identify any Food and Drug Administration (FDA) clearance or approval number for the Collagen P.I.N as currently marketed on https://inductiontherapies.com/what-is-collagen-pin/, https://inductiontherapies.com/collagen-pin-benefits/, and https://inductiontherapies.com/collagen-pin-faqs/ with the intended use for mechanically inducing a micro injury in the living layer of the skin which triggers new collagen and elastin synthesis, and is marketed to treat skin concerns including fine lines and wrinkles, aging, sun damaged skin, peri-oral rhytides, melasma, hyperpigmentation issues, acne scarring and rough texture.

We request that you provide us with the following information:

- FDA clearance or approval number for the Collagen P.I.N.
- The basis for your determination of whether or not you are required to obtain FDA clearance or approval for the Collagen P.I.N.
- The current version of the device labeling, including but not limited to your instructions for use.

In addition, we request that a written response be submitted within 30 days of receipt of this letter. The response and any further correspondence regarding this matter should reference the Document Number, listed above, and should be submitted to:

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Market Intelligence, WO66-3600
Division of Regulatory Programs 3
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

If you have questions relating to this matter, you may contact Felicia Brayboy at 301-796-8086, or log onto our web site at www.fda.gov for general information relating to FDA device requirements.

Sincerely,

Cynthia Chang -S

Cynthia J. Chang, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health